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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on the substantiation of a health claim related to vitamin D and contribution to the normal function of the immune system pursuant to Article 14 of Regulation (EC) No 1924/2006

EFSA Journal

Link to article, DOI:
10.2903/j.efsa.2015.4096

Publication date:
2015

Document Version
Publisher's PDF, also known as Version of record

Link back to DTU Orbit

Citation (APA):
EFSA Journal (2015). *EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on the substantiation of a health claim related to vitamin D and contribution to the normal function of the immune system pursuant to Article 14 of Regulation (EC) No 1924/2006*. Europen Food Safety Authority. the EFSA Journal Vol. 13(5) No. 4096 https://doi.org/10.2903/j.efsa.2015.4096

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European Food Safety Authority

EFSA Journal 2015;13(5):4096

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to vitamin D and contribution to the normal function of the immune system pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from VAB-nutrition, submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to vitamin D and contribution to the normal function of the immune system. The Panel considers that vitamin D is sufficiently characterised. Contribution to the normal function of the immune system is a beneficial physiological effect for children. The Panel had previously assessed a claim on vitamin D and contribution to the normal function of the immune system with a favourable outcome. The target population was the general population. The Panel considered that vitamin D plays a regulatory role in the functioning of the immune system. The Panel considers that the role of vitamin D in the functioning of the immune system applies to all ages, including children. The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin D and contribution to the normal function of the immune system. The following wording reflects the scientific evidence: "Vitamin D contributes to the normal function of the immune system". The target population is children from 3 to 18 years of age.

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KEY WORDS

vitamin D, immune system, children, health claims

[1] On request from the Competent Authority of France following an application by VAB-nutrition, Question No EFSA-Q-2014-00826, adopted on 22 April 2015.

[2] Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Hendrik Van Loveren, Hans Verhagen and Peter Willatts, for the preparatory work on this scientific opinion.

Suggested citation: EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on the substantiation of a health claim related to vitamin D and contribution to the normal function of the immune system pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2015;13(5):4096, 7 pp. doi:10.2903/j.efsa.2015.4096

Available online: www.efsa.europa.eu/efsajournal

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SUMMARY

Following an application from VAB-nutrition, submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to vitamin D and contribution to the normal function of the immune system.

The scope of the application was proposed to fall under a health claim referring to children's development and health.

The food constituent that is the subject of the health claim is vitamin D, which is an essential nutrient and is measurable in foods by established methods. Vitamin D occurs naturally in foods and is authorised for addition to foods and for use in food supplements. The Panel considers that vitamin D is sufficiently characterised.

The claimed effect proposed by the applicant is that vitamin D "contributes to the normal function of the immune system". The target population proposed by the applicant is children from 3 to 18 years of age. The Panel considers that contribution to the normal function of the immune system is a beneficial physiological effect for children.

The Panel had previously assessed a claim on vitamin D and contribution to the normal function of the immune system with a favourable outcome. The target population was the general population. The Panel considered that vitamin D plays a regulatory role in the functioning of the immune system. The Panel considers that the role of vitamin D in the functioning of the immune system applies to all ages, including children.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin D and contribution to the normal function of the immune system.

The following wording reflects the scientific evidence: "Vitamin D contributes to the normal function of the immune system".

In order to bear the claim, a food should be at least a source of vitamin D as per Annex to Regulation (EC) No 1924/2006. Such amounts can easily be consumed as part of a balanced diet. The target population is children from 3 to 18 years of age. Tolerable Upper Intake Levels have been established for vitamin D in this age group.

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BACKGROUND

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of this Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 19/11/2014.
- The scope of the application was proposed to fall under a health claim referring to children's development and health.
- The scientific evaluation procedure started on 19/12/2014.
- During its meeting on 22/04/2015, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to vitamin D and contribution to the normal function of the immune system.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: vitamin D and contribution to the normal function of the immune system.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of vitamin D, a positive assessment of its safety, nor a decision on whether vitamin D is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address

VAB-nutrition, 1 rue Claude Danziger, 63100 Clermont-Ferrand, France.

Food/constituent as stated by the applicant

According to the applicant, the food constituent for which the claim is made is vitamin D.

Health relationship as claimed by the applicant

According to the applicant, vitamin D contributes to the normal function of the immune system.

A number of mechanistic studies were provided which, according to the applicant, demonstrate that vitamin D plays a role in both innate and adaptive immune function and, as such, contributes to the normal function of the immune system.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "vitamin D contributes to the normal function of the immune system".

Specific conditions of use as proposed by the applicant

According to the applicant, in order to bear the claim, a food should at least be a source of vitamin D as per Annex to Regulation (EC) No 1924/2006.

The target population proposed by the applicant is children from 3 to 18 years of age.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is vitamin D, which is an essential nutrient and is measurable in foods by established methods.

Vitamin D occurs naturally in foods as vitamin D_2 (ergocalciferol) and vitamin D_3 (cholecalciferol). Different forms of vitamin D are authorised for addition to foods and for use in food supplements (Annex II of Regulation (EC) No 1925/2006,[5] Annex II of Directive 2002/46/EC,[6] Annex III of Directive 2006/141/EC,[7] Annex IV of Directive 2006/125/EC,[8] Directive 2001/15/EC[9]). This evaluation applies to vitamin D naturally present in foods and those forms authorised for addition to

[5] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.
[6] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.
[7] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC Text with EEA relevance. OJ L 401, 30.12.2006, p. 1–33.
[8] Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children. OJ L 339, 6.12.2006, p. 16–35.
[9] Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses. OJ L 52, 22.2.2001, p. 19–25.

foods (Annex II of Regulation (EC) No 1925/2006, Annex II of Directive 2002/46/EC, Annex III of Directive 2006/141/EC, Annex IV of Directive 2006/125/EC, Directive 2001/15/EC).

The Panel considers that the food constituent, vitamin D, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is that vitamin D "contributes to the normal function of the immune system". The target population proposed by the applicant is children from 3 to 18 years of age.

The Panel considers that contribution to the normal function of the immune system is a beneficial physiological effect for children.

3. Scientific substantiation of the claimed effect

The Panel has previously assessed a claim on vitamin D and contribution to the normal function of the immune system with a favourable outcome (EFSA NDA Panel, 2010). The target population was the general population.

The Panel considered that vitamin D plays a regulatory role in the functioning of the immune system (EFSA NDA Panel, 2010).

The Panel considers that the role of vitamin D in the functioning of the immune system applies to all ages, including children.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin D and contribution to the normal function of the immune system.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "Vitamin D contributes to the normal function of the immune system".

5. Conditions and restrictions of use

The Panel considers that, in order to bear the claim, a food should be at least a source of vitamin D as per Annex to Regulation (EC) No 1924/2006. Such amounts can easily be consumed as part of a balanced diet. The target population is children from 3 to 18 years of age. Tolerable Upper Intake Levels (UL) have been established for vitamin D in this age group and have been set at 50 µg/day for children aged 1 to 10 years and 100 µg/day for adolescents aged 11 to 17 years (same as for adults) (EFSA NDA Panel, 2012).

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, vitamin D, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is that vitamin D "contributes to the normal function of the immune system". The target population proposed by the applicant is children

from 3 to 18 years of age. Contribution to the normal function of the immune system is a beneficial physiological effect for children.

- A cause and effect relationship has been established between the dietary intake of vitamin D and contribution to the normal function of the immune system.
- The following wording reflects the scientific evidence: " Vitamin D contributes to the normal function of the immune system".
- In order to bear the claim, a food should be at least a source of vitamin D as per Annex to Regulation (EC) No 1924/2006. Such amounts can easily be consumed as part of a balanced diet. The target population is children from 3 to 18 years of age.

DOCUMENTATION PROVIDED TO EFSA

1. Health claim application on vitamin D and contribution to the normal function of the immune system pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0430_FR). November 2014. Submitted by VAB-nutrition.

REFERENCES

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010. Scientific Opinion on the substantiation of health claims related to vitamin D and normal function of the immune system and inflammatory response (ID 154, 159), maintenance of normal muscle function (ID 155) and maintenance of normal cardiovascular function (ID 159) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(2):1468, 17 pp. doi:10.2903/j.efsa.2010.1468

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2012. Scientific Opinion on the Tolerable Upper Intake Level of vitamin D. EFSA Journal 2012;10(7):2813, 45 pp. doi:10.2903/j.efsa.2012.2813